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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

August 7, 2003

REF- 2003-DAL-WL-15

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Robert P. Thoni, D.V.M., President
Kilgore Veterinary Associates, Inc.
3404 South Henderson Blvd.
Kilgore, Texas 75662

Dear Dr. Thoni:

Food & Drug Administration investigators conducted an inspection of your firm on February 4/5, 2003. The inspection documented significant violations of the Federal Food, Drug, and Cosmetic Act (the FD & C Act). As a result of these violations, unapproved new animal drugs were distributed in interstate commerce, a violation under Section 501 (a) (5) of the Act. Unapproved new drugs authorized by your prescriptions are not permitted under Title 21 Code of Federal Regulations (CFR) §530.20 because conditions for permitting extra-label animal and human drug use in food-producing animals have not been met. Since these drugs prescribed are not approved, they are deemed unsafe and as such, are adulterated within the meaning of Section 501(a) (5) of the FD & C Act.

Title 21 CFR Part 530 – Extralabel Drug Use in Animals provides for a veterinarian or pharmacist to compound animal drugs on the lawful written order of a licensed veterinarian only if certain conditions are met. The conditions include the requirement that the compounding be within the context of a valid Veterinary Client Patient Relationship (VCPR), and that the compounding is conducted with the use of already approved drug products. Compounding, using bulk active pharmaceutical ingredients is not permitted. You are distributing in interstate commerce unapproved new animal drugs, a violation under section 501 (a) (5) of the FD & C Act.

The inspection confirmed that you participated in a verbal agreement in the capacity of the consulting/prescribing veterinarian for drugs compounded by [redacted] from about November 1, 2001, through November, 2002. In the agreement, established by yourself and [redacted] Salesman of [redacted] you provide veterinary services to farm and ranch clients within a [redacted] mile radius of your firm by prescribing veterinary drugs compounded by [redacted] During the time of this agreement, dispensing records, maintained by [redacted] identify you as the authorizing/prescribing veterinarian for the following compounded drugs:

dipyrone	fluphanazine*
gentamycin sulfate*	fluoxetine*
Enrofloxacin*	methylprednisolone
Ivermectin*	ketoprofen
phenylbutazone	flunixin

The drugs identified with the asterisks denote drugs that are prohibited for extra label use in food producing animals under Title 21 CFR 530.41.

Records provided from your veterinary files document the following example of your activities during your agreement with [redacted]

> On 4/16/02, you authorized [redacted]s dispensing of the compounded injectable prescription drugs, enrofloxacin (Baytril), ivomectin (Ivermectin), and flunixine (Banamine) to [redacted] This authorization was made without you establishing a valid VCPR with the firm. Your veterinary files do not include documentation that the drugs were identified for a particular species of animals to be treated; diagnosis of a specific disease(s); dosage and time period for treatment; or route of administration, cautionary statements, or a withdrawal time(s) established for animals that may be marketed for consumption as human food.

FDA's investigation found that [redacted] used the above prescription veterinary drugs in the treatment of cattle. Ivermectin 2% sterile injection present at [redacted] was labeled with a withdrawal time that you, as the prescribing veterinarian, had taken no part in establishing. Additionally, the enrofloxacin injection was labeled in part "** FOR USE AS DIRECTIED * Dr. THONI, ROB **". You confirmed, you have no records establishing the need for these compounded drug products. In fact, FDA approved versions of these drugs are available in the marketplace.

Our inspection documented dispensing by [redacted] and various RX orders authorized by Dr. Rob Thoni, DVM as veterinarian of record during the time of your agreement, of a compounded equine antibiotic, Gentamycin 100MG/ML – 500ML injectable drug to [redacted], and other livestock producers/growers in [redacted] You were unable to provide patient/client records to support a VCPR with these operations. Investigations found the drug was being used for medical treatment of starter calves. These producers/growers include:

[redacted] on 9/10/02, RX [redacted]
on 9/23/02, RX [redacted]
on 10/15/02, RX [redacted]

I have attached a copy of the Form FDA-483, Inspectional Observations issued by the investigators and discussed with you at the completion of the inspection on February 5, 2003.

By prescribing, and authorizing the dispensing of the above listed drugs by [redacted] you as the veterinarian accepting responsibility for the medical treatment of animals, have caused the compounding of unapproved new animal drugs, as well as, the shipment of those drugs in interstate commerce. These drugs were compounded, with the use of bulk active pharmaceutical ingredients (APIs), for administration in food producing animals and horses. [redacted] holds no approval of applications for the above listed drugs as required pursuant to Section 512(a)(1)(A) of the FD & C Act. The drugs are deemed unsafe, and therefore, are adulterated within the meaning of Section 501(a)(5) of the FD & C Act.

As a licensed prescribing veterinarian, you hold the responsibility to know and understand federal and state laws that apply to you and your veterinary practice. The only legal compounding of animal drugs is provided for under the Animal Medicinal Drug Use Clarification Act of 1994 and its implementing regulations at 21 Code of Federal Regulations (CFR) Part 530 – Extralabel Drug Use in Animals. 21 CFR 530.13 provides for a veterinarian or pharmacist to compound animal drugs on the lawful written order of a licensed veterinarian only if certain conditions are met. The conditions include the requirement that the compounding be within the context of a valid VCPR, and that the compounding is conducted with the use of already approved drug products. Compounding, using bulk active pharmaceutical ingredients is not permitted.

You should take prompt action to correct the violations encountered and assure that your future orders for prescription veterinary drugs, and the authorized dispensing of those drugs for/to animals of your clientele, are in fact legal products, and their administration follows all required conditions for use under the FD & C Act and regulations. Failure to correct the conditions of your veterinary practice and to establish procedures whereby such conditions do not recur may result in further investigations and possible Agency actions against regulated products and or responsible individuals.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step taken, or to be taken, to correct the violations and prevent their recurrence. Please include copies of any available documentation demonstrating corrections have been made. You should address your response to the attention of James R. Lahar, Compliance Officer at the above letterhead address.

Sincerely yours,

Michael A. Chappell
Dallas District Director

MAC/JRL